K130482

APR 2 9 2013

5.0 510(k) Summary

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the Combat Ready Clamp (CRoC™) device is provided below.

Device Common Name: Vascular Clamp

Device Proprietary Name: Combat Ready Clamp (CRoC™)

Submitter:
Combat Medical Systems, LLC
5845-D Yadkin Road
Fayetteville, NC 28303

Contact:
Calley Herzog
Consultant
Biologics Consulting Group, Inc.
Phone: 720-883-3633
Email: cherzog@bcg-usa.com

Date Prepared: **April 18, 2013**

Classification Regulation: 21 CFR 870.4450, Class II, 510(k)

Panel: Cardiovascular

Product Code: DXC

Predicate Device: K102025, Combat Ready Clamp

Indication for Use:
The Combat Ready Clamp (CRoC™) is indicated for use in the battlefield to control difficult bleeds in the inguinal and axilla areas.

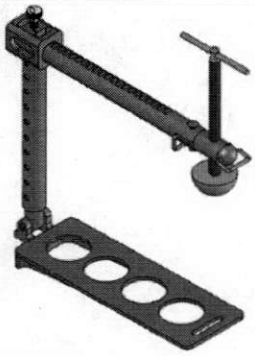
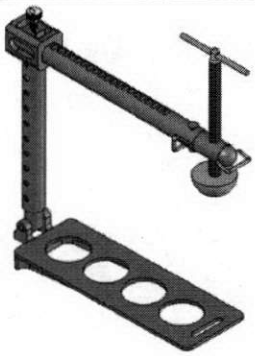
Device Description:
The CRoC™ is designed to be used by emergency medical personnel in the battlefield. The device is designed to control bleeding in anatomical areas where standard tourniquets cannot be used. The device can be used instead of manual pressure, allowing the medic to attend to other injuries. The Combat Ready Clamp is used to control a difficult bleed for up to 4 hours until the injured can be transferred to evacuation personnel or other medical personnel for further treatment.

Performance Data:
To establish the substantial equivalence the CRoC™ was tested with a cadaver model to show that it was capable of stopping simulated vessel blood pressure in the axilla area.

Substantial Equivalence:

Based on technological characteristics and performance data the CRoC™ has been shown to be substantially equivalent to the predicate device, the Combat Ready Clamp as cleared in K102025.

Device Comparison Table

	New Device	**Predicate Device**
510(k) Number	K130482	K102025
Device Name	Combat Ready Clamp (CRoC™)	Combat Ready Clamp (CRoC™)
Manufacturer	Combat Medical Systems, LLC	Combat Medical Systems, LLC
Picture		
Indication	The Combat Ready Clamp is indicated for use in the battlefield to control difficult bleeds in the inguinal and axilla areas.	The Combat Ready Clamp is indicated for use in the battlefield to control difficult bleeds in the inguinal area.
Dimensions	8"x12 1/4"x9" (extended)	8"x12 1/4"x9" (extended)
Weight	1.25 lbs with disc attached	1.25 lbs with disc attached

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 29, 2013

Combat Medical Systems, LLC
C/O Biologics Consulting Group, Inc.
13417 Quivas St.
Westminster, Colorado 80234
Attention: Calley Herzog

Re: K130482
Trade/Device Name: Combat Ready Clamp (CRoC™)
Regulation Number: 21 CFR 807.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: DXC
Dated: February 25, 2013
Received: February 26, 2013

Dear Ms. Herzog:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4.0 Indications for Use Statement

510(k) Number (if known): K130482

Device Name: Combat Ready Clamp (CRoC™)

Indications For Use:

The Combat Ready Clamp is indicated for use in the battlefield to control difficult bleeds in the inguinal and axilla areas.

Prescription Use __X___ AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Matthew G Hillebrenner